

INITIAL STATEMENT OF REASONS

California Code of Regulations, Title 22, Division 5

Chapter 1. General Acute Care Hospitals

Article 10. Hospital Administrative Penalties

The purpose of these proposed regulations is to implement California Health and Safety Code (H&SC) Section 1280.3 by adopting criteria for assessment of administrative penalties against general acute care hospitals (GACHs), acute psychiatric hospitals (APHs), and special hospitals (SHs) for violation of any requirement of hospital licensure.

Problem Statement: The Department cannot assess maximum administrative penalties against a licensee of a general acute care hospital, an acute psychiatric hospital, or a special hospital until regulations are adopted. H&SC Section 1280.3 authorizes the director of the Department of Public Health (Department) to assess an administrative penalty against a licensee of a general acute care hospital, an acute psychiatric hospital, or a special hospital for a violation of any requirement of licensure. H&SC § 1280.3 (b) also requires the Department to adopt regulations establishing criteria for assessing an administrative penalty against a hospital and specifically provides eight criteria that must be included in the regulations. The Department is currently authorized to assess administrative penalties for violations that constitute immediate jeopardy under H&SC § 1280.1. When these regulations become effective, the maximum penalties for immediate jeopardy violations will increase and the Department will also be authorized to assess administrative penalties for violations that do not constitute immediate jeopardy.

Objectives: Broad objectives of this proposed regulatory action are to:

- Implement H&SC Section 1280.3.
- Adopt criteria for assessment of administrative penalties against hospitals for deficiencies that constitute immediate jeopardy, as well as less serious violations that do not constitute immediate jeopardy.
- Establish a procedure for penalty calculation that accounts for all criteria required by law.
- Enforce compliance with the full scope of hospital licensure requirements by assessing civil money penalties for failure to comply with the law.

- Protect the health and safety of hospital patients.

Benefits: Anticipated benefits from this proposed regulatory action are:

- More effectively enforce compliance with licensure requirements by increasing the maximum penalties against hospitals for the most serious deficiencies that constitute immediate jeopardy.
- Deter less serious violations that do not constitute immediate jeopardy.
- Promote statewide consistency in assessment of administrative penalties by applying specific criteria to calculate the amount of the penalty.

Background:

The California Department of Public Health (CDPH), Licensing and Certification (L&C) Program has regulatory oversight for more than 30 types of health care facilities and providers. L&C licenses and certifies approximately 7,000 health facilities in the State, including hospitals and long-term health care facilities. L&C fulfills its responsibilities through the process of licensing and inspecting facilities to ensure compliance with State laws and regulations and certifying facilities for compliance with federal laws and regulations governing participation in the Medicare and Medicaid programs. CDPH is the State Survey Agency acting for the federal Center of Medicare and Medicaid Services (CMS) to certify that the health facilities accepting Medicare and Medi-Cal payments meet federal participation requirements.

In 2006, in response to concerns that the administrative penalties for hospitals were too low to effectively compel compliance, the Legislature enacted Senate Bill (SB) 1312, which provided the Department with a greatly enhanced civil money penalty enforcement system for all acute care settings. Prior to this, state law authorized the Department to assess against a hospital that failed to correct a deficiency, a civil penalty in an amount not to exceed \$50 per patient affected by the deficiency for each day the deficiency continued beyond the date specified for correction. SB 1312 allowed the Department to issue monetary penalties to hospitals for violations of state law requirements, which the Legislature believed would provide incentives for hospitals to attain and maintain regulatory compliance. The Assembly Floor Analysis, dated 8/29/06, stated “civil penalties are a central step in enforcing compliance with regulations, reflecting the consequences for failure to comply with licensing regulations. As such, this bill has been amended to give authority to DHS [now CDPH] to issue administrative penalties to hospitals for noncompliance with state licensing laws.”

The original penalties were for violations that were considered to meet the standard for immediate jeopardy as defined in H&SC Section 1280.1. An administrative penalty could have been issued to a hospital for deficiencies constituting immediate jeopardy to

the health or safety of a patient in an amount not to exceed \$25,000 per violation. Immediate jeopardy is defined as a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Additionally, SB 1312 allowed CDPH, upon the adoption of regulations, to administer an administrative penalty for violations that do not constitute immediate jeopardy in an amount up to \$17,500 per violation. The bill required CDPH to include the following factors when developing regulations to establish criteria to assess administrative penalties against hospitals:

- Patient's physical and mental condition.
- Probability and severity of the risk that the violation presents to the patient.
- Actual financial harm to patients, if any.
- Nature, scope, and severity of the violation.
- Facility's history of compliance with related state and federal statutes and regulations.
- Factors beyond the facility's control that restrict the facility's ability to comply with H&SC Division 2, Chapter 2 or the rules and regulations promulgated thereunder.
- Demonstrated willfulness of the violation.
- Extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from occurring.

CDPH was prohibited from assessing administrative penalties for minor violations.

In 2008, SB 541 amended H&SC Section 1280.1 to raise the immediate jeopardy penalty for general acute care GACHs, APHs, and SHs from a maximum of \$25,000 per violation to a maximum of \$50,000 for the first penalty, a maximum of \$75,000 for the second and up to \$100,000 for the third and every subsequent penalty. This law provided that any violation that occurs after three years of a previous violation shall be considered the first violation, given that the facility has demonstrated substantial compliance with all state licensing laws and other federal laws. These new penalties took effect for violations occurring after January 1, 2009. In addition, CDPH must consider all factors and the special circumstances of small and rural hospitals in order to protect access to care in those hospitals.

SB 541 also amended H&SC Section 1280.3 to authorize increased administrative penalties for immediate jeopardy violations at up to \$75,000 for a first immediate jeopardy violation, up to \$100,000 for a second immediate jeopardy violation, and up to \$125,000 for the third and every subsequent violation, effective upon the Department's adoption of implementing regulations. This law also provided that any violation that occurs after three years of a previous violation shall be considered the first violation, given that the facility has demonstrated substantial compliance with all state licensing

laws and other federal laws. This law also authorized increased administrative penalties against GACHs, APHs, and SHs for non-immediate jeopardy violations from \$17,500 to up to \$25,000 per violation, effective upon adoption of implementing regulations.

Reasonable Alternatives to the Regulation and Reasons for Rejecting Those Alternatives

In addition to the process employed by CMS and its State Survey Agencies to evaluate the seriousness of deficiencies and determine the appropriate amount of federal civil money penalties, the Department also researched civil penalty standards used in the states of Florida, Texas, Rhode Island, and New York. However, it was determined that these statutes provided even less guidance in the assessment of penalties than H&SC Section 1280.3. The New York Public Health Code has general authority to assess a civil penalty of up to \$2000 for any violation, up to \$5000 for a subsequent violation within twelve months for a serious threat to the health or safety of any individual, and up to \$10,000 if the violation directly resulted in serious physical harm to any patient. (N.Y. Pub. Health Code § 12.) However, this New York law lacks the desired specificity needed to calculate a penalty using all criteria listed in H&SC Section 1280.3.

The Department also reviewed an administrative penalty regulation adopted by the Department of Managed Health Care at Cal. Code of Regulations (CCR), title 28, §1300.86 “Assessment of Administrative Penalties.” Although this regulation lists eleven criteria to choose from, there are no procedures for penalty calculation and no guidance on how to weigh the criteria.

The Department considered giving equal weight to all eight criteria in H&SC Section 1280.3, but this alternative was not chosen because some criteria are more important than others for the protection patient health and safety. For example, the nature, scope, and severity of the violation are more important to the protection of public health than financial harm to patients.

The Department also considered the option of administrative penalties for deficiencies that resulted in no actual harm with a potential for no more than minimal harm. This alternative was rejected in favor of a standard that was more consistent with State citation penalties and federal civil money penalties for long-term health care facilities, as discussed under Section 70952 “Definitions” below. The Department was also concerned about the financial impact of the additional workload of assessing and enforcing civil penalties at this level.

As to the proposed regulations, the Department has made an initial determination that no reasonable alternative considered or otherwise identified and brought to its attention

would be more effective in carrying out the purpose for which this action is proposed, or would be as effective as and less burdensome to affected private persons than the proposed action or would be more cost effective to affected private persons, or as effective in implementing the intent of H&SC Section 1280.3.

Rationale for the Regulations

The proposed regulations enhance the ability of the Department to carry out administrative enforcement in a manner consistent with H&SC Section 1280.3 by providing a standard and systematic approach to the assessment of administrative penalties. This approach is primarily based on the seriousness of the deficiency, as measured by its severity and the extent of noncompliance from hospital licensure requirements. A penalty matrix is used to select an “initial penalty” that corresponds to the classification of the violation. The Department may apply adjustment factors to the initial penalty based on specific criteria, including the patient’s physical condition. The cumulative adjustments to the initial penalty are combined produce a base penalty. Additional adjustment factors, pertaining to immediate correction of the violation and the hospital’s compliance history, can be applied to the base penalty. After this series of adjustments, the resulting penalty assessed is the final penalty. The proposed regulations provide criteria for these adjustments, including the criteria required by H&SC Section 1280.3, and a practical method for the Department to determine an appropriate penalty allowing for professional judgment, while maintaining statewide consistency.

This approach was chosen by the Department because of its similarity to the criteria and the procedures that CMS uses to assess the seriousness of deficiencies prior to assessment of civil money penalties on long-term health care facilities (42 CFR §§ 488.404, 488.438(f)). To aid in the assessment of deficiencies, CMS developed a tool called “Assessment Factors Used to Determine the Seriousness of Deficiencies Matrix,” commonly referred to as the “Scope and Severity Grid,” which categorizes violations based on the severity of harm or risk of harm, and whether the scope of the violation is isolated, pattern, or widespread. This grid is used by CMS and State Survey Agencies, such as CDPH, as an aid in evaluating seriousness of a violation in order to select appropriate enforcement remedies. CDPH surveyors have been trained by CMS and are well-versed in the use of the parameters on this grid to evaluate a wide range of deficiencies and to recommend civil money penalties to CMS. The U.S. health care industry is also familiar with how this grid is used by CMS.

In an effort to increase national consistency in amounts, CMS developed a Civil Money Penalty (CMP) Analytic Tool, which includes a worksheet and CMP grids, but its use is not mandatory for States. To calculate a penalty, CMP Analytic Tool starts with a base amount based on the CMP scope and severity grids, but it also includes additional

amounts that are added to the base amount for repeat deficiencies, culpability, and history of noncompliance.

The Department also reviewed a worksheet called “Civil Money Penalty Schedule,” developed by the Michigan Department of Licensing and Regulatory Affairs, Division of Licensing & Certification, which the State of Michigan uses to calculate and recommend civil money penalties to CMS. Under the Michigan procedure, the penalty amount is determined by first selecting the appropriate base amount on one of the CMP scope and severity grids, and then additional penalties may be added to the base amount for various factors, such as compliance history, repeat violation, and culpability.

For the foregoing reasons, the Department has determined that these regulations constitute the appropriate approach for assessment of hospital administrative penalties. A detailed rationale for each section follows:

§ 70951. Applicability.

This section describes the applicability of Article 10 as it pertains to the assessment of hospital administrative penalties. Subdivision (a) states that Article 10 of Chapter 1 of Division 5 of Title 22 CCR applies only to the assessment of administrative penalties issued to general acute care hospitals pursuant to H&SC Section 1280.3. Additional provisions are not necessary for special hospitals because these hospitals are regulated under Article 10. (See 22 CCR §§ 70034, 70223 (i), 70233 (e).)

Subdivision (a)(1) provides that Article 10 does not apply to minor violations as defined in the regulations. This provision is necessary to make clear when Article 10 applies and that a penalty cannot be assessed for a minor violation under H&SC Section 1280.3 (c).

Subdivision (a)(2) provides that Article 10 does not apply to the settlement of an enforcement action. Settlement negotiations may take other factors into account. For example, penalties may be compromised based on litigation factors. This provision is necessary to make clear that Article 10 applies only to the assessment of penalties and not to settlements.

Subdivision (a)(3) provides that Article 10 shall not apply to penalties that may be assessed by the Department under laws other than H&SC Section 1280.3. These laws include H&SC Sections 1278.5 [whistleblower protections], 1280.15 [medical information breach], 1280.4 [adverse event reporting], 1317.3 [transfer protocols and policies], 1317.4 (f) [whistleblower retaliation], and 1317.6 [H&SC Div. 2, Ch. 2, Art. 7]. That these statutes are intended to operate independently from H&SC Section 1280.3 is apparent from the fact that they provide for different methods of penalty calculation (per day, per patient, or per violation), different procedures for issuance and appeal of civil

penalty (citation procedures, an informal conference, or a formal hearing under the Administrative Procedures Act), different criteria for penalty setting, and different maximum penalty amounts. For example, H&SC Section 1280.3 requires consideration of eight specific criteria for penalty setting, whereas H&SC Section 1317.6 specifies only four criteria.

In light of these significant differences, the proposed method of penalty calculation is not appropriate for the calculation of penalties under other statutes. Therefore, this provision is necessary to exclude these violations from this rulemaking. The department intends to develop separate regulation proposals for H&SC Section 1280.15 regarding breaches of patient medical information privacy, and H&SC Section 1280.4 regarding adverse event reporting.

H&SC Section 1280.3, subdivision (e) states that these regulations shall only apply to incidents occurring on or after the effective date of the regulations. Subdivision (b) makes clear that these penalty regulations apply only to incidents occurring on or after the effective date of this regulation. Subdivision (c) provides that incidents occurring prior to the effective date of this regulation remain subject to administrative penalties as described in Health and Safety Code Section 1280.1 (d). These provisions are necessary to clarify that after the effective date of these regulations, the Department may assess administrative penalties for incidents occurring before the effective date, but the penalty amounts will be determined in accordance with the law in effect at the time the violation occurred, even if that law becomes “inoperative” after the effective date of these regulations (H&SC § 1280.1 (f)). The Department believes that the Legislature intended the term “inoperative” to mean that H&SC Section 1280.1 is not operative or applicable to violations occurring on or after the effective date of these regulations, and conversely that Section 1280.1 continues to apply to violations occurring before the effective date. Otherwise, the Department would have no recourse to penalize hospitals that violate the law immediately before the effective date of these regulations and there is not sufficient time for the Department to issue an administrative penalty before the statute becomes “inoperative.” Such a significant gap in enforcement authority would allow an unfair “break” to some violators and would frustrate the primary purpose of the law to protect public health.

The legislative history of H&SC Section 1280.3 supports the Department’s interpretation. On the date SB 1312 passed, the bill’s author, Senator Elaine Alquist, submitted a letter to the Senate Legislative (Daily) Journal regarding SB 1312, stating that the reason the fines referenced in Section 1280.1 will no longer be in effect once the regulations are promulgated for Section 1280.3 is “to assure that hospitals will not be doubly-penalized.” (Senator Elaine K. Alquist and Assembly Member Wilma Chan, letter to Greg Schmidt, Senate Sect., Aug. 31, 2006, Sen. J. (2005-2006 Reg. Sess.) p.

5606.) It is apparent that the legislative intent of Section 1280.1, subdivision (f) was to prevent the assessment of two administrative penalties--under H&SC Sections 1280.1 and 1280.3—for any single violation. Subdivision (c) of Section 70951 closes an unintended and potentially serious gap in the Department's enforcement authority in a manner consistent with the statutory intent to avoid double-penalizing hospitals.

The dates found in this section should correspond with the date the proposal takes effect under State law. Therefore, the dates found in this provision are proposed to coincide with the effective date of this proposal. However, because the effective date cannot be determined, the Department proposes to authorize the Office of Administrative Law (OAL) to insert the date for clarity.

Subdivision (b) also states that as to incidents occurring on or after the effective date of this regulation, the hospital's compliance history prior to the effective date of this regulation, including deficiencies constituting immediate jeopardy, shall be considered in assessing administrative penalties as provided in this article and under Health and Safety Code Section 1280.3 (a) and (b). This is necessary to clarify that although the administrative penalties issued under H&SC Section 1280.3 depend whether the violation occurred on or after on the effective date of this regulation, the Department will consider the hospital's past compliance, including violations that occurred before the effective date, in assessing penalties.

§ 70952. Definitions.

This section defines terms used in H&SC Section 1280.3 and Article 10. These definitions are necessary to clarify and to ensure consistency in the terminology used in these regulations. Each of the definitions is discussed below.

“Actual financial harm” is defined as a concrete financial loss for medical costs incurred by a patient, where the loss was not covered or reimbursed by health insurance. H&SC Section 1280.3 (b)(3) requires the department to adopt regulations establishing administrative penalty criteria, including “actual financial harm to patients, if any.” This definition clarifies that there must be an actual, concrete financial loss for medical costs incurred by a patient that was not paid for by the patient's health insurance coverage. The financial loss is limited to medical costs and does not include lost wages or other costs usually recovered under tort law, because medical costs have a more direct relationship to the violation that is the subject of the administrative penalty and are not dependent on variables, such as whether or not the patient was employed. This is consistent with the statutory purpose of administrative penalties which is to enforce compliance with licensing requirements. In addition, this definition clarifies that medical costs that are covered or reimbursed by a patient's health insurance do not result in actual financial harm to the patient, to the extent that the insurance covered the medical

bills. The plain language meaning of “actual financial harm to patients” excludes financial harm to insurance companies that paid the patients’ medical bills. This definition is necessary to clarify and make specific a criterion for calculation of the administrative penalty.

“Deficiency” is defined as a licensee’s failure to comply with any law relating to the operation or maintenance of a hospital as a requirement of licensure under the H&SC or the California Code of Regulations (CCR), title 22, division 5. The term “deficiency” is generally used in the field of health care facility regulation to mean noncompliance or a violation of law. See 22 CCR § 78031. This definition is necessary to clarify a basic term that is used in H&SC Section 1280.3 and in these regulations.

“Hospital licensing requirements,” “hospital licensing standards,” and “licensure requirements” are defined to refer to the licensing requirements applicable to hospitals, including hospital fair pricing /discount/charity care policy requirements, in the H&SC and the regulations adopted thereunder. H&SC § 1280.3 authorizes administrative penalties against a hospital for violation of Health and Safety Code, Division 2, Chapter 2, and Division 107, Part 2, Chapter 2.5, Article 1 and the regulations adopted thereunder. The definition of “immediate jeopardy” is tied to noncompliance with “requirements of licensure.” (H&SC § 1280.3 (g).) This definition is necessary to clarify a basic term used in H&SC Section 1280.3 and in the proposed regulations.

“Minor violation” is defined as any violation of law relating to the operation or maintenance of a hospital that the department determines has only a minimal relationship to the health or safety of hospital patients. This provision is similar to the standard used by the Department to issue notices of violation without a citation penalty assessment to long-term health care facilities under H&SC Section 1424 (i) and 22 CCR § 72701, and establishes some consistency in enforcement policies between hospital administrative penalties and the citation penalty system for long-term health care facilities. H&SC Section 1280.3, subdivision (c) provides that the department shall not assess an administrative penalty for “minor violations.” The Department has determined that the only violations that do not warrant an administrative penalty are those that have only a minimal relationship to patient health or safety. For example, whether or not a true copy of the hospital license is conspicuously posted as required by 22 CCR § 70123 or a copy of the hospital annual report is submitted to the Department as required by 22 CCR § 70735 has little to no relationship to patient health or safety. This regulation also states that this definition does not apply to violations of the hospital fair pricing/discount/charity care policy standards found at H&SC §§ 127400 *et seq.*, because there is a separate definition of “minor violation” in § 70959 for that type of violation. This definition is necessary to clarify a term used in H&SC Section 1280.3

and in the proposed regulations that will determine when an administrative penalty will not be assessed.

“Repeat deficiencies” are defined to mean violations of hospital licensing requirements or federal certification standards in the same or substantially similar regulatory grouping of requirements, which violations are found during an inspection, subsequently corrected, and found again at a subsequent inspection. H&SC 1280.3 (b)(5) requires the department to adopt regulations establishing administrative penalty criteria, including the “facility’s history of compliance with related state and federal statutes and regulations.” Section 70953 on penalty calculation includes consideration of repeat deficiencies in the evaluation of a hospital’s compliance history. The language in this definition is similar to the federal CMS definition of “repeated deficiencies” for long-term care facilities in 42 CFR § 488.438 “Civil money penalties: Amount of penalty,” which provides for an increase in the federal civil penalty amount for repeated deficiencies. This definition is necessary to clarify a term used in the proposed regulations.

“Substantial compliance” is defined to mean a level of compliance with state hospital licensing standards and federal hospital certification standards, such that any identified deficiencies pose no greater risk to patient health or safety than the potential for causing minimal harm.

H&SC 1280.3 (a) sets escalating maximum administrative penalties for immediate jeopardy violations depending on whether the immediate jeopardy violation is the first, second, or third or subsequent administrative penalty. However, the statute provides that a subsequent immediate jeopardy violation may be considered a “first” administrative penalty, if during the three year period prior to the violation: (1) the hospital has not received any additional immediate jeopardy violations, and (2) the hospital “is found by the department to be in substantial compliance with all State and federal licensing laws and regulations.” This statutory provision is vague and confusing because hospitals are certified, not licensed, by CMS to provide services to patients under the federal Medicare and Medicaid programs, and the Department is the State Agency that inspects and certifies health facilities under a contract with CMS. This regulation clarifies that applicable federal hospital standards are the federal laws that set forth the conditions of participation for hospitals in the Medicare program, 42 CFR Part 482.

The language of the State definition is similar to the federal definition of “substantial compliance” in 42 CFR § 488.301, relating to the certification and enforcement of compliance for long-term care facilities. Both definitions provide that a finding of “substantial compliance” requires that any identified deficiencies pose no greater risk to patient health or safety than the potential for causing minimal harm. This definition is necessary to clarify a term used in H&SC Section 1280.3 and in the proposed

regulations that set forth how the maximum penalty for an immediate jeopardy violation is determined.

The terms “willfulness,” “willfully” and “willful” are defined to mean that the person doing an act or omitting to do an act intends the act or omission, and knows the relevant circumstances connected with the act or omission. This definition is identical to the definition in H&SC Section 1248.8 (c) which clarifies the penalty for violations of law governing outpatient settings, including the term “willfulness of the violation.” This regulation is necessary to clarify a term that is used in H&SC Section 1280.3 and in these regulations and to maintain consistency with other definitions in the H&SC.

“Willful violation” is defined to mean that the licensee, through its employees or contractors, willfully commits an act or omits to do an act with knowledge of the facts which bring the act within the deficiency that is the basis for an administrative penalty. Section 1280.3 (b)(3) requires the department to adopt regulations establishing administrative penalty criteria, including “the demonstrated willfulness of the violation.” The definition of “willful violation” applies the concept of “willfulness” and the rule of non-delegable duties of licensees to deficiencies, so that a hospital is responsible for the acts or omissions of its employees or contractors. The well-established rule of non-delegable duties is that the licensee, operating a business through employees, must be responsible to the licensing authority for its conduct in the exercise of his license. (See *California Assn. of Health Facilities v. Dept. of Health Services* (1997) 16 Cal.4th 284.) This regulation is necessary to clarify a term that is used in H&SC § 1280.3 and in these regulations.

§ 70953. Penalty Calculation.

This section states that administrative penalties issued pursuant to H&SC Section 1280.3 will be assessed following the procedures set forth in these regulations, Article 10. It also states that the penalty calculated under Article 10 for any single deficiency will not exceed the penalties specified in statute. As fully discussed above under “*Rationale for the Regulations*,” this section is necessary to establish procedures for penalty calculation and to make clear that penalties are subject to any applicable statutory maximum.

§ 70954. Determining the Initial Penalty for Each Violation.

This section details how the initial penalty will be determined for each violation. The matrix presented in this section is the tool the penalty assessors will use to arrive at the appropriate initial penalty for a deficiency.

Subdivision (a). This subdivision states that an initial penalty will be determined for each violation based the nature, scope and severity of the deficiency. This provision is

necessary to specify the considerations for determining an initial penalty, and to make clear that this section addresses the statutory mandates of H&SC Section 1280.3 (b)(2) and (b)(4), to take into account, among other criteria, the nature, scope, and severity of the violation, and the probability and severity of the risk that the violation presents to patients.

Subdivision (b)--Severity of the deficiency: This subdivision and related subdivisions, (b)(1) and (b)(2), describe how severity of actual and potential harm to patients is factored into determining the initial penalty for each violation.

Subdivision (b)(1): This subdivision states that severity of actual and potential harm to patient health or safety will be considered when using the initial penalty matrix in Subdivision (d). The severity scale reflects the legislative intent of H&SC 1280.3 that violations of requirements take on greater or lesser significance depending upon the actual or potential harm that did or could occur, in the judgment of the Department, as a result of the facility's deficiencies. The scale lists six levels of increasing severity ranging from potential for more than minimal harm up to immediate jeopardy causing patient death. These severity levels are derived from the factors used by CMS to determine the seriousness of a deficiency found in 42 CFR § 488.404, and to determine the amount of federal civil money penalties under 42 CFR § 488.438 (f). However, the State severity levels divide immediate jeopardy into three levels—likely to cause serious injury or death of a patient, caused serious injury to a patient, and caused the death of a patient. These additional levels are necessary to impose higher penalties for immediate jeopardy deficiencies that caused serious injury or death.

The proposed severity levels provide a tool to determine the seriousness of identified deficiencies and guide assessment of administrative penalties. Level 5 and Level 6 deficiencies reflect the most serious consequences of noncompliance with licensure requirements, where the deficiency has resulted in serious injury or death. Level 4 deficiencies are nearly as serious, but have not yet resulted in serious injury or death. Although deficiencies classified in Severity Level 4, Level 5, and Level 6 are all categorized as immediate jeopardy, the result or outcome of the deficiency would determine whether the deficiency falls into one level or another. Level 4 acknowledges that potential severe risk to patients exists but has not yet been realized, while Level 5 is assigned only when at least one instance of actual serious injury has occurred, and Level 6 is assigned when patient death has occurred. Level 3 deficiencies are those that result in actual harm that is less severe than serious injury or death. Level 2 is for deficiencies that pose a potential for more than minimal harm, but have not yet resulted in actual harm. Level 1 is for minor violations with a potential for no more than minimal harm, but have not yet resulted in actual harm.

Subdivision (b)(2): This subdivision states that the patient's physical condition and mental condition, and the probability and severity of the risk that the violation presents to patients will be considered in determining the level of severity using the initial penalty matrix in Subdivision (d). This provision clarifies that the penalty will be assessed using the matrix to apply the criteria required by H&SC 1280.3 (b)(1) and (b)(2).

Subdivision (c): This subdivision discusses the scope or extent of noncompliance with requirements of licensure and is necessary to make clear how the Department uses extent of noncompliance when determining the initial penalty for each violation using the matrix in Subdivision (d). Related subdivisions (c)(1) through (c)(3), are discussed below.

Subdivision (c)(1): This subdivision states that the extent of deviation from requirements will be determined when using the matrix in Subdivision (d). This subdivision is necessary to implement, in part, the statutory mandate of H&SC Section 1280.3 (b)(4) that requires consideration of, among other things, the nature and scope of the violation.

Subdivision (c)(2): This subdivision defines the categories of "extent of noncompliance" from requirements. These categories, "major," "moderate," and "minimal," are defined in related Subdivisions (c)(2)(A) through (c)(2)(C). This language is necessary to make clear how to categorize the extent of noncompliance and to provide consistent definitions for the extent of noncompliance categories.

Subdivision (c)(3): This subdivision demonstrates how to determine the extent of noncompliance of a violation. This subdivision is needed to clarify, by using an example, how the extent of noncompliance can vary for a single requirement depending on the specifics of the violation.

Subdivision (d): This subdivision presents the matrix used to determine the initial penalty for each deficiency. The parameters for the matrix are the severity and the extent of noncompliance from the regulatory requirement as described in Subdivisions (b) and (c). The scope and severity levels as presented in the matrix are intended to visually assist the application of the standards to the facts of each deficiency, and to enhance consistency of penalty assessments. The percentages on the matrix were chosen to result in increasingly higher initial penalties corresponding to the increasing seriousness of the deficiency, as determined by the Department. The penalty amounts are scaled from zero [no penalty for minor violations] to 100 percent of the applicable statutory administrative penalty. The maximum amounts are in the matrix cells representing the most serious violations--those that fall into the category of an immediate jeopardy causing patient death. This matrix is similar to the grid in the CMS Civil Money Penalty (CMP) Analytical Tool used by CMS, and to the grid used by Michigan Department of Licensing and Regulatory Affairs, Division of Licensing and

Certification to calculate and recommend “per instance” federal civil money penalties to CMS. This provision is needed to present the tool to determine the initial penalty amount needed as the first step to calculation of the base penalty and then a final penalty.

Subdivision (d) describes how the matrix is used to determine the initial penalty for a deficiency by selecting a penalty percentage from the range provided in the matrix cell that corresponds to the appropriate extent of noncompliance and the severity of harm parameters, and locating the matrix cell with the corresponding penalty percentage. The penalty percentages in the matrix cells apply to the appropriate corresponding maximum penalty for immediate jeopardy deficiencies in H&SC Section 1280.3 (a) and non-immediate jeopardy deficiencies in H&SC Section 1280.3 (b), which are listed in regulation for clarity and ease of use.

The following examples demonstrate how penalty percentages in the matrix cells apply to the appropriate corresponding maximum penalty for immediate jeopardy deficiencies:

1. The initial penalty for a deficiency at severity level 5 and moderate noncompliance is 70% of the maximum immediate jeopardy penalty, which is \$75,000, \$100,000, or \$125,000 depending on the number of immediate jeopardy deficiencies the hospital has received. Assuming that the deficiency is the hospital’s first immediate jeopardy deficiency, the maximum amount would be \$75,000, and applying the 70% factor would produce an initial penalty of \$52,500.
2. The initial penalty for a deficiency at severity level 3 and major noncompliance is 100% of the maximum non-immediate jeopardy penalty of \$25,000, resulting in an initial penalty of \$25,000.

H&SC Section 1280.3 (e) provides that the “regulations shall apply only to incidents occurring on or after the effective date of these regulations.” On that date, incidents constituting immediate jeopardy will be subject to maximum penalties of \$75,000 for a first immediate jeopardy violation, \$100,000 for a second violation, and \$125,000 for the third and every subsequent violation. However, H&SC Section 1280.3 (a) provides that “[a]n administrative penalty issued after three years from the date of the last issued immediate jeopardy violation shall be considered a first administrative penalty,” if specific conditions are satisfied. Because the penalty assessment regulations should apply to deficiencies based on the date the incident occurred, not the date of penalty issuance, Subdivision (d) clarifies that an immediate jeopardy penalty may be considered a first administrative penalty if the date the violation occurred is over three years from the date of violation of the last issued immediate jeopardy penalty. The length of time between a violation and the date the penalty is issued varies considerably

depending on the complexity of the investigation, and basing the escalation of the maximum penalties on the dates of violation is more consistent with fairness and effective enforcement of the laws as well as with H&SC Section 1280.3 (e). To date, the Department has been determining immediate jeopardy penalties under H&SC Section 1280.1(d) based on the dates of violation, and there is no reason this procedure should change under H&SC Section 1280.3.

Although these regulations apply only to incidents occurring on or after the effective date of these regulations, the Department will consider the hospital's compliance history prior to the effective date of the regulation, including deficiencies constituting immediate jeopardy, in assessing an administrative penalty (see Section 70951 (b)). For example, if the Department intends to issue an immediate jeopardy penalty to a hospital for a violation that occurs one month after the effective date, in determining the amount of the administrative penalty, the Department would consider the hospital's compliance history before that date. If the compliance history shows only one prior immediate jeopardy penalty for a violation that occurred two years before the effective date, the penalty at hand would be considered a second subsequent administrative penalty under H&SC section 1280.3 (a).

Under H&SC Section 1280.3 (a), resetting of the immediate jeopardy penalty count to a first violation is also conditioned on a determination by the Department that the hospital has been in substantial compliance for over three years and has not received any additional immediate jeopardy violations. Subdivision (d) makes clear that the substantial compliance requirement applies to the three year period prior to the date of the violation that is the subject of the penalty calculation. The term "substantial compliance" is defined in Section 70952 as a level of compliance with state hospital licensing standards and federal hospital certification standards, such that any identified deficiencies pose no greater risk to patient health or safety than the potential for causing minimal harm. As discussed above, this definition is similar to the federal definition of "substantial compliance" in 42 CFR § 488.301, relating to the certification and enforcement of compliance for long-term care facilities.

The bottom of the matrix indicates that Severity Level 1 is a minor violation that results in no penalty. H&SC Section 1280.3, subdivision (c) provides that the department shall not assess an administrative penalty for "minor violations." In Section 70952, "minor violation" is defined as any violation of law relating to the operation or maintenance of a hospital that the department determines has only a minimal relationship to the health or safety of hospital patients. Thus, the administrative penalty scheme incorporates the concept of substantial compliance, whereby minor deficiencies that have only a minimal relationship to the health or safety of patients and constitute no more than a potential for

minimal harm are not sanctioned with an administrative penalty under H&SC Section 1280.3.

§ 70955. Initial Penalty Adjustment Factors.

This section describes the factors that the Department considers to adjust the initial penalty amount. This provision is necessary to specify the factors for adjusting an initial penalty and to provide a consistent basis for raising or lowering the initial penalty.

Subdivision (a)(1): This subdivision states that the patient's physical and mental condition is a factor to consider in adjusting a violation's initial penalty and provides guidelines to assist in determining the amount of penalty adjustment. This provision is necessary to address the statutory mandate of H&SC Section 1280.3 (b)(1) to take into account, among other criteria, the patient's physical and mental condition in assessing the penalty.

The guideline states that the initial penalty is adjusted upward by 5 percent, if the violation caused actual harm to the patient at severity level 3 or 5 resulting in a physical or mental impairment that substantially limits one or more of the major life activities of a patient, or the loss of bodily function, if the impairment or loss lasts more than three days. The initial penalty is adjusted upward by 10 percent, if the impairment or loss lasts more than seven days or is still present at the time of discharge from the hospital, or involves the loss of a body part. This language is based on the definition of "serious disability" in H&SC Section 1279.1(d), which is part of the statute that requires hospitals to report adverse events to the Department. Because the term "serious disability" is incorporated into the majority of adverse events listed in the statute, the Department, hospitals and others in the healthcare community are familiar with this concept, and it is a reasonable guide for adjusting the initial penalty upward based on the patient's physical or mental condition. The percentages for upward adjustment of the penalty are scaled to correspond to the degree of harm to the patient. There is no upward adjustment for patient injury resulting in death because the Initial Penalty Matrix provides a higher penalty percentage for Severity Level 6, "immediate jeopardy to patient health or safety that caused the death of a patient," than Level 5, "immediate jeopardy to patient health or safety that caused serious injury to a patient."

Subdivision (a)(2): This subdivision states the initial penalty shall be adjusted upward by 1 percent, if the violation caused actual financial harm to the patient. This provision is necessary to address the statutory mandate of H&SC Section 1280.3 (b)(3) to take into account, among other criteria, the financial harm to patients, if any, in assessing the penalty. The term "actual financial harm" is defined in Section 70952. The percentage of upward adjustment for financial harm is significantly smaller than the percentages for mental or physical injury in Subdivision (a), as is consistent with the legislative focus on

serious patient care violations and “never” events (serious medical harm resulting from preventable medical mistakes). It is necessary to permit the Department to make its determination on financial harm to the patient based on information acquired by the department during the normal course of the investigation, so that the Department is not required to expend scarce resources seeking evidence of financial harm not readily available during an inspection.

Subdivision (a)(3): H&SC Section 1280.3 (b)(5) requires the Department to consider factors beyond the hospital’s control that restrict the hospital’s ability to comply with licensure requirements in Health and Safety Code, Division 2, Chapter 2 and regulations adopted thereunder. Under these circumstances, this regulation provides that the initial penalty shall be adjusted downward by 5 percent, if the hospital developed and maintained disaster and emergency programs as required by state and federal law that were appropriately implemented during a disaster. This provision is necessary to encourage disaster planning and emergency preparedness by providing a penalty reduction to hospitals that implement appropriate disaster and emergency programs during a disaster or emergency.

Subdivision (a)(4): This subdivision states that the initial penalty shall be adjusted upward by 10 percent if the deficiency was the result of a willful violation. This provision is necessary to address the statutory mandate of H&SC Section 1280.3 (b)(3) to consider, among other criteria, the “demonstrated willfulness of the violation.” The terms “willfulness,” “willfully” and “willful” are defined in Section 70952 to mean that the person doing an act or omitting to do an act intends the act or omission, and knows the relevant circumstances connected with the act or omission. This upward penalty adjustment of 10 percent is necessary to deter intentional violations of law.

Subdivision (b): This subdivision clarifies that after the adjustment factors are applied to the initial penalty, the resulting percentage could be higher or lower than the original percentage.

§ 70956. Base Penalty.

This section defines the term “base penalty” as the cumulative adjusted initial penalty as determined under Sections 70954 and 70955. This section is necessary to define the term “base penalty” for further penalty adjustments in Section 70957, and to make clear that the base penalty may exceed the statutory maximum for the purpose of penalty calculation, so long as the final penalty does not exceed the statutory maximum.

§ 70957. Adjustments to the Base Penalty.

This section describes the two criteria used to adjust the base penalty in the last step of the penalty calculation leading to the final penalty. Each adjustment factor is discussed below in related Subdivisions (a) and (b).

Subdivision (a): Immediate correction of the violation. This regulation is necessary to address the statutory mandate of H&SC Section 1280.3 (b)(8) to take into account, among other criteria, the “extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring.” This subdivision states that when a hospital promptly corrects the noncompliance for which the administrative penalty was imposed, the base penalty shall be adjusted downward by 20 percent, if the hospital has satisfied specific conditions relating to immediate correction and self-reporting. This downward adjustment does not apply to deficiencies that constitute immediate jeopardy violations or repeat deficiencies.

Subdivision (b): Compliance History. This regulation is necessary to address the statutory mandate of H&SC Section 1280.3 (b)(5) to take into account, among other criteria, the hospital’s “history of compliance with related state and federal statutes and regulations.” This term is defined in Subdivision (b) as the hospital’s record of compliance with hospital licensure requirements under the H&SC and the regulations adopted thereunder, and with, the federal regulations for hospitals that participate in the Medicare program. The time frame specified for examining a hospital’s compliance history is three years, based on three year period in H&SC Section 1280.3 (a).

Subdivision (b)(1) states that the base penalty is adjusted downward by five percent if hospital inspections within the last three years prior to the date of violation indicated no state or federal deficiencies that resulted in patient harm or immediate jeopardy (severity levels 3 through 6, inclusive). This provision provides a penalty reduction to hospitals that have consistently avoided serious violations. Subdivision (b)(2) states that an upwards adjustment of five percent is made if the hospital has demonstrated a history of noncompliance—three or more repeat deficiencies that pose a risk of more than minimal harm to patient health or safety (severity levels 2 through 6, inclusive). Repeated violations of the same or similar regulatory standards are important in evaluating a hospital’s compliance history because they indicate that the facility has been unable or unwilling to correct a violation, that previous penalties were not high enough to deter the hospital from violating again, and that a higher penalty is warranted.

§ 70958. Final Penalty:

This section states that the final penalty consists of the base penalty, with any adjustments pursuant to Section 70957, and that the final penalties are never more than the statutory maximums. This section is necessary to make clear how final penalty is calculated.

§ 70959. Penalties for Violations of Hospital Fair Pricing Policies Requirements.

As noted in Section 70953 [penalty calculation], administrative penalties for violations of requirements relating to hospital fair pricing policies (H&SC §§ 124700 *et seq.*) are calculated under this section, rather than the other regulations in Article 10. The laws regulating hospital fair pricing policies for discount payment and charity care (“discount and charity care policy laws”) were enacted in 2006 to protect the financial interests of uninsured and underinsured consumers of healthcare, and are enforced by the Department as conditions of hospital licensure. H&SC Section 1280.3 was amended in 2007 to authorize the Department to assess administrative penalties for these violations, except for minor violations.

Because the other regulations in Article 10, including the Initial Penalty Matrix, are so heavily focused on patient health and safety, the Department believes that it would be less confusing and less cumbersome to have a separate regulation for assessment of administrative penalties for violations of discount and charity care policy laws, including a separate definition of “minor violation.” This regulation is similar to the standard procedures for penalty calculation, except that the criteria relating primarily to patient health and safety were eliminated from the process, including the patient’s physical and medical condition, probability and severity of risk to the patient, severity of actual patient harm, and disasters and emergencies beyond the hospital’s control.

The regulation provides that the penalty calculation begins with an initial penalty which is based on the extent of noncompliance with a requirement. The extent of noncompliance is divided into three categories with corresponding initial penalties as follows: major noncompliance--\$2000, moderate noncompliance-- \$1000, and minimal non-compliance—no penalty. Although these initial penalty amounts are set considerably lower than those in the penalty matrix, they are appropriate in view of the fact that these types of violations do not involve actual physical injury or risk of physical harm to the patient.

The regulation provides upward adjustments to the initial penalty of 5 percent if the violation caused actual financial harm to the patient as defined in Section 70952, and 10 percent if there was a willful violation, as defined in Section 70952. The cumulative adjusted initial base penalty produces a base penalty, which is subject to further adjustments for immediate correction of the violation and for compliance history. These adjustments are similar to the adjustments discussed in greater detail elsewhere in this document (above at §§ 70155-70158), except that the upward percentage adjustment for actual financial harm to patients is set at a higher level because the discount and charity care policy laws are intended for the protection of the financial interests of healthcare consumers. Also, the compliance history adjustment is simplified because

the factors of actual patient harm and immediate jeopardy have been removed as they are not relevant to these types of violations.

§ 70960. Small and Rural Hospitals.

This regulation provides an option for a small and rural hospital (as defined in H&SC § 124840) that has been assessed an administrative penalty to submit a written request for an extended payment plan, if immediate, full payment of the penalty would cause extreme financial hardship to the hospital. The small and rural hospital may also request reduction of the penalty, if extending the payment over a period of time would cause extreme financial hardship to the hospital. This regulation is necessary to address the statutory mandate of H&SC Section 1280.3 (h) that the Department “take into consideration the special circumstances of small and rural hospitals . . . in order to protect access to quality care in those hospitals,” and to describe a process for the Department to review these special circumstances. The regulation describes when and how to submit a request to the Department, what that request must contain, and the basis for approval or denial of the request.

Chapter 2. Acute Psychiatric Hospitals

Article 8. Hospital Administrative Penalties.

§ 71701. Applicability.

This section describes the applicability of Article 8 as it pertains to the assessment of hospital administrative penalties under H&SC 1280.3. This section states that Article 8 of Chapter 2 of Division 5 of Title 22 CCR applies only to the assessment of administrative penalties issued to acute psychiatric hospitals.

Subdivision (a)(1) provides that Article 8 does not apply to minor violations as defined in Section 70952. Subdivision (a)(2) provides that Article 8 does not apply to the settlement of an enforcement action. Subdivision (a)(3) provides that Article 8 shall not apply to penalties that may be assessed by the Department under laws other than H&SC Section 1280.3. Subdivision (b) makes clear that these penalty regulations apply only to incidents occurring on or after the effective date of this regulation, and that as to such incidents, the hospital’s compliance history prior to the effective date of this regulation, including deficiencies constituting immediate jeopardy, will be considered in assessing administrative penalties. Subdivision (c) states that incidents occurring prior to the effective date of this regulation remain subject to administrative penalties as described in Health and Safety Code Section 1280.1 (d). The language and rationale for these subdivisions are identical to those subdivisions in Section 70951 “Applicability”

of the administrative penalty regulations for general acute care hospitals, fully discussed above.

§ 71702. Penalty Assessment.

This section states that administrative penalties for acute psychiatric hospitals assessed pursuant to H&SC Section 1280.3 will be assessed following the procedures set forth in Chapter 1, Article 10, with the exception of Section 70959, relating to hospital fair pricing policy laws which do not apply to acute psychiatric hospitals. It also states that the penalty calculated for any single deficiency will not exceed the penalties specified in H&SC section 1280.3. This section is necessary to establish procedures for penalty calculation by incorporating by reference of the penalty setting procedures in Article 10, and to make clear that penalties are subject to applicable statutory maximums. Incorporation by reference reduces duplication and makes clear that, with minor exceptions, the same procedures for assessment of administrative penalties apply general acute care hospitals, acute psychiatric hospitals, and special hospitals.

§ 71703. Small and Rural Hospitals.

This regulation provides an option for a small and rural hospital (as defined in H&SC § 124840) that has been assessed an administrative penalty to make a written request for modification of an administrative penalty under the procedures set forth in Section 70960. This regulation is necessary to address the statutory mandate of H&SC Section 1280.3 (h) that the Department “take into consideration the special circumstances of small and rural hospitals . . . in order to protect access to quality care in those hospitals,” and to describe a process for the Department to review these special circumstances. Incorporation by reference reduces duplication and makes clear that, with minor exceptions, the same procedures for assessment of administrative penalties apply general acute care hospitals, acute psychiatric hospitals, and special hospitals.

Studies, Reports, or Documents Relied Upon

- Title 42 Code of Federal Regulations §§ 488.404, 488.438(f), (10/1/11).
- Centers for Medicare & Medicaid Services, *State Operations Manual*, Chapter 7, sections 7400.5.1 and 7400.5.2, pp. 91-96, “Factors That Must Be Considered When Selecting Remedies,” with graph titled “Assessment Factors Used to Determine the Seriousness of Deficiencies Matrix” (Rev. 63, 09-10-10).
- Memorandum from Centers for Medicare & Medicaid Services, Director of Survey and Certification Group to State Survey Agency Directors, June 22, 2007 “Civil Money Penalty (CMP) Analytic Tool.”

- Michigan Department of Licensing and Regulatory Affairs, Bureau of Health Systems, Division of Licensing & Certification, “Civil Money Penalty Schedule.”
- Senator Elaine K. Alquist and Assembly Member Wilma Chan, letter to Greg Schmidt, Senate Secretary, August 31, 2006, Senate Journal (2005-2006 Reg. Sess.) p. 5606.

Consistency and Compatibility with Existing State Regulations

The Department evaluated this proposal as to whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department’s existing general regulations and those regulations specific to hospital licensure. An internet search of other state agency regulations was also performed and it was determined that no other state regulation addressed the same subject matter and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

Economic Impact Assessment

The Department has determined that the regulations affect the following as described:

1. **The creation or elimination of jobs within the State of California.** This proposal will not result in any increase or elimination of jobs within California.
2. **The creation of new businesses or the elimination of existing businesses within the State of California.** This proposal will not have any impact and/or effect on the creation or elimination of new business within the state of California.
3. **The expansion of businesses currently doing business within the State of California.** This proposal will not have any effect on how business is impacted within the State of California.
4. **The benefits of the regulation to the health and welfare of California residents, and increases worker safety.** This proposal was introduced to effectively enforce compliance with licensure requirements by increasing the maximum penalties against hospitals for the most serious deficiencies that constitute immediate jeopardy, and to deter less serious violations that do not constitute immediate jeopardy. At the same time, the regulations promote statewide consistency in assessment of administrative penalties by applying specific criteria by which to calculate the amount of the penalty, and finally the main benefit is aimed at improving the health, safety and welfare of California residents while

within acute care hospitals by applying stiffer penalties and applying penalties to the less serious violations that effect a patient's health, welfare and or safety.

**STATEMENTS OF DETERMINATIONS
and
ECONOMIC IMPACT ASSESSMENT**

A. ALTERNATIVES CONSIDERED

The Department has determined that no reasonable alternative considered or otherwise identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed, or would be as effective as and less burdensome to affected private persons than the proposed action or would be more cost effective to affected private persons and equally effective in implementing the intent of H&SC Section 1280.3.

The Department reviewed alternatives to be considered by initially reviewing the process employed by Centers for Medicare & Medicaid Services (CMS) and its State Survey Agencies to evaluate the seriousness of deficiencies and calculate the appropriate amount of federal civil money penalties. The Department also researched civil penalty standards used in the states of Florida, Texas, Rhode Island, and New York. However, it was determined that these statutes provided even less guidance in the assessment of penalties than H&SC Section 1280.3. The New York Public Health Code has general authority to assess a civil penalty of up to \$2,000 for any violation, up to \$5,000 for a subsequent violation within twelve months for a serious threat to the health and safety of any individual, and up to \$10,000 if the violation directly resulted in serious physical harm to any patient. (N.Y. Pub. Health Code § 12.) However, this New York law lacks the desired specificity needed to calculate a penalty using all eight criteria listed in H&SC Section 1280.3.

The Department also reviewed a penalty regulation adopted by the Department of Managed Health Care at Cal. Code of Regulations (CCR), title 28, §1300.86 “Assessment of Administrative Penalties.” Although this regulation lists eleven criteria to choose from, there are no procedures for penalty calculation and no guidance on how to weigh the criteria.

The Department considered giving equal weight to all eight criteria in H&SC Section 1280.3, but this alternative was not chosen because some criteria are much more important than others for the protection of patient’s health and safety.

The Department also considered the option of administrative penalties for deficiencies that resulted in no actual harm with a potential for minimal harm. This alternative was rejected in favor of a standard that was more consistent with state citation penalties and

federal civil money penalties for long-term health care facilities. The Department was also concerned about the financial impact of the additional workload of assessing and enforcing civil penalties at this level.

B. LOCAL MANDATE DETERMINATION

CDPH has determined that the proposed regulatory action would have an adverse economic impact on California business enterprises. However, it should be noted that only in the event that a GACH, APH or SH is in violation of the licensing standards, where the violation resulted in more than the potential for minimal harm to a patient(s) will they be subject to receiving an administrative penalty for an immediate jeopardy or a non-immediate jeopardy type violation. Therefore, only hospitals that are in noncompliance with licensure requirements stand to be negatively impacted by a proposed administrative penalty. Hospitals who maintain the required licensure standards and are in good standing with both state and federal requirements will not be negatively affected by this mandate and not be subject to financial penalties.

The final amount of the penalty against a hospital will be assessed and dependent on the number of occurrences, the scope and severity of their actions. The greater degree of harm, the higher the penalty amount, the number of times a penalty is repeated, the greater the amount awarded.

It is not anticipated that this mandate will affect the ability of California businesses (hospitals) to compete with businesses in other states.

The Department has determined that the regulation would not affect individuals.

The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

C. ECONOMIC IMPACT ASSESSMENT

The Department has determined that the regulations affect the following as described:

3. **The creation or elimination of jobs within the State of California.** This proposal will not result in any increase or elimination of jobs within California.
4. **The creation of new businesses or the elimination of existing businesses within the State of California.** This proposal will not have any impact and or effect on the creation or elimination of new business within the state of California.

3. **The expansion of businesses currently doing business within the State of California.** This proposal will not have any effect on how business is impacted within the State of California.
4. **The benefits of the regulation to the health and welfare of California residents, and increases worker safety.** This proposal was introduced to effectively enforce compliance with licensure requirements by increasing the maximum penalties against hospitals for the most serious deficiencies that constitute immediate jeopardy, and to deter less serious violations that do not constitute immediate jeopardy. At the same time, the regulations promote statewide consistency in assessment of administrative penalties by applying specific criteria by which to calculate the amount of the penalty, and finally the main benefit is aimed at improving the health, safety and welfare of California residents while within acute care hospitals by applying stiffer penalties and applying penalties to the less serious violations that effect a patient's health, welfare and or safety.

D. EFFECTS ON SMALL BUSINESSES

The Department has determined that there will be an effect on small business (hospital), since all GACHs, APHs & SHs fall under the regulation parameters despite their size and or location. However, the Legislature did include specific guidelines and considerations to be included within the regulation to provide appropriate consideration and exceptions for the small and rural hospital community to be used when being assessed an administrative penalty in order to prevent any possible excessive financial burden that may cause the hospital to go out of business. The guidelines include alternatives that provide the Department with the option of reducing the final penalty amount to avoid possible closure of a facility due to creating excessive financial burden, and by providing a period of time with which to make payments for any penalty that cannot be paid upon receipt.

E. EFFECTS ON HOUSING COSTS

The Department has determined the regulations will have no impact on housing costs.